REMARKS

I. Status of the Claims

Claims 26-49, 51-58 and 61-67 are pending in this application and claims 31, 44-49, 61 and 62 are withdrawn.

Claims 63 and 67 are amended herein. New claim 68 is added. Support for the amendment to claims 63 and 67 are found throughout the application as originally filed, for example, page 13, lines 13-20 of the specification as originally filed. Support for new claim 68 is found throughout the application as originally filed, for example, page 37, lines 7-12. Applicants respectfully submit that no new matter is introduced.

Claims 26-30, 32-43, 51-58, 63-67 are rejected. Claims 26-30, 32-43, 51-53, 58, 63-65 and 67 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,165,193 to Greene, Jr. et al. ("Greene") in view of U.S. Patent No. 3,921,629 to Richter et al. ("Richter"). Claims 54, 55 and 66 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Greene in view of Richter and further in view of U.S. Patent No. 6,784,273 to Spaans et al. ("Spaans"). Claims 56 and 57 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Greene in view Richter and further in view of U.S. Patent No. 6,231,590 to Slaikau et al. ("Slaikeu").

In view of the above amendments and following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

II. Response to Obviousness Rejection Under 35 U.S.C. §103(a) over Greene in view of Richter

Claims 26-30, 32-43, 51-53, 58, 63-65, 67 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,165,193 to Greene, Jr. et al. ("Greene") in

view of U.S. Patent No. 3,921,629 to Richter et al. ("Richter"). Applicants respectfully traverse this ground of rejection.

Applicants' independent claim 63, as amended, recites:

> 63. A device for treating a vascular malformation, wherein said vascular malformation has an internal wall defining an internal volume containing blood under pressure, the device comprising:
>
> **at least one implant comprising a reticulated elastomeric matrix**, said at least one implant being expandable from a first configuration to a second configuration, the second configuration being larger than the first configuration and defining an implant volume in said second configuration,
>
> wherein said first configuration is sized for delivery into the internal volume of the vascular malformation,
>
> wherein said second configuration is fitted at least in part to a shape of the internal wall, providing physical support to the internal wall of the vascular malformation, and
>
> **wherein the implant volume is less than the internal volume of the vascular malformation**.

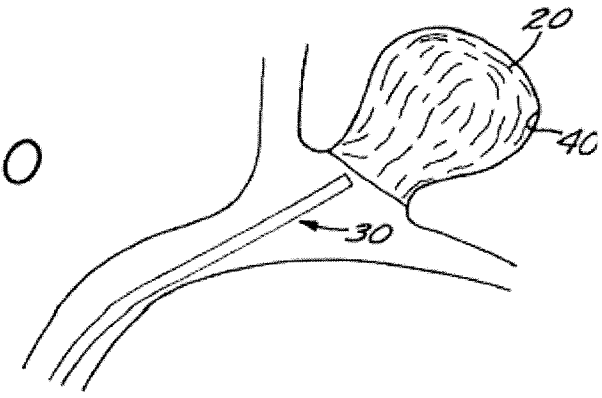
A rejection under 35 U.S.C. §103(a) requires the establishment of a *prima facie* case that the claimed subject matter, including all claim elements, would have been obvious to a person having ordinary skill in the art on the basis of either a single prior art reference or more than one reference properly combined. As no such *prima facie* case has been established for these claims, Applicants respectfully traverse these rejections, as set forth more fully below.

A. Greene Does Not Teach or Suggest an Implant Wherein the Implant Volume is Less Than the Internal Volume of the Vascular Malformation

Applicants' independent clams 63 and 67, as amended, recite "wherein the implant volume is less than the internal volume of the vascular malformation." In contrast, Greene describes "[a] vascular implant formed of a compressible foam material has a

compressed configuration from which it is expansible into a configuration **substantially conforming to the shape and size of a vascular site** to be embolized." (Greene, Abstract)(emphasis added). In an expanded configuration, the implant described by Greene "is large enough **substantially to fill the vascular site**." (Greene, col. 6, lines 63-65)(emphasis added). Alternatively, the implant described by Greene "in its initial, precompressed configuration, it is 'life size', i.e., approximately **the same size as the vascular site**." (Greene, col. 6 line 66 to col. 7, line 1)(emphasis added). The Office Action relies on Figure 10, reproduced below, of the Greene reference as a basis for "an expanded configuration." (See Office Action, p.3).

FIG. 10



As can be seen in Figure 10, the expanded configuration of Greene is substantially the same shape and size as the vascular site and completely fills the vascular site. Greene does not contemplate a vascular implant having a volume less than the internal volume of a vascular malformation. Accordingly, Greene does not teach or suggest an implant defining an implant volume in an expanded configuration, "wherein the implant volume is less than the internal volume of the vascular malformation" as recited by the amended independent claims 63 and 67.

B. Greene Does Not Teach or Suggest an Elastomeric Matrix

Applicants' independent claim 63 specifically recites "at least one implant comprising a reticulated **elastomeric matrix.**" Similarly, Applicants' independent claim 67

recites "a biodurable reticulated **elastomeric matrix**." The specification states that such matrices are "compressible and exhibit resilience in their recovery." (Specification, page 23, line 7).

Greene describes an implant having "a hydrophilic, macroporous, polymeric, **hydrogel** foam material," which exhibits different physical properties, and provides a completely different type of polymer as compared to an **elastomeric** matrix recited by Applicants' claims. (*See* Greene, col. 3, lns. 50-53). Moreover, Greene requires that the implant be compressed and be set "in its compressed configuration by heating and/or drying." (Greene, col. 7, lns. 27-28). A continuing compressive force is not required to maintain the hydrogel disclosed by Greene in a compressed configuration. An elastomeric matrix does not and cannot be maintained in a compressed configuration solely by heating and/or drying. As defined by Applicants' specification, the elastomeric matrix is resilently compressible and cannot be held in a compressed configuration once a compressive force is removed.

In addition, Greene describes that its implant expands by "hydrophilic hydration of the implant material" and/or "from the filling of its pores with blood." (Greene, col. 8, 22-27). Specifically, if the implant was formed from "a non-hydrophilic material, its expansion [would be] due to the latter mechanism **only**." (Greene, col. 8, lns. 26-27)(*emphasis added.*). Greene restricts its description to implants comprising materials that only expand based on the described mechanisms. Greene does not contemplate any alternative mechanisms for expanding an implant. Therefore, Greene's hydrogel cannot and does not resiliently recover to substantially the pre-compression state without the addition of external forces (*e.g.*, fluid pressure). Applicants' claims recite an implant comprising a reticulated elastomeric matrix, which is capable of resiliently recovering without absorbing aqueous fluids or filling its pores with blood

or any other liquid. Accordingly, the implant of Greene is not what is called for in the claim language of the present application.

C. Richter Does Not Cure the Deficiencies of Greene

The Office Action concedes that the "Greene reference does not disclose the matrix is reticulated." (Office Action, p.3). However, the Office Action attempts to cure the deficiencies of Greene with Richter. Specifically, the Office contends that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the polymer matrix of Green [sic] reference a fully reticulated matrix in the manner taught by Richter reference for rapid fluid absorption to expand the implant rapidly to fill the aneurysm." (Office Action, p.3). Applicants respectfully disagree.

A reasonable expectation of success is required to establish a *prima facie* case that the claimed subject matter would have been obvious to a person having ordinary skill in the art. See In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); MPEP §2143.02. The cited references do not provide one of ordinary skill in the art with a reasonable expectation that a reticulated foam may be successfully obtained from the hydrogel material of Greene. Richter describes polyurethane foam suitable for preparing sponges. (*See* Richter, col. 5, lines 30-32). The polyurethane foam may be reticulated or non-reticulated. (*See id.*, col. 5, lines 41-42). According to Richter, "[r]eticulated foam may be prepared by a physical or chemical reticulation process." (*Id.*, col. 5, lines 43-45). Greene describes an implant having "a hydrophilic, macroporous, polymeric, **hydrogel** foam material." (*See* Greene, col. 3, lns. 50-53). Greene describes exemplary materials for the hydrogel, which includes polyvinyl alcohol foam (PAF) gel and PHEMA. (*See id.*, col. 6, lines 42-48). The hydrogel described by Greene is a completely different material, having different chemical compositions and different physical properties as compared to the polyurethane foam described by Richter. There is no teaching or

suggestion from either Richter or Greene that a reticulated elastomeric matrix can be obtained from a hydrogel.

The Examiner contends that one of ordinary skill in the art would have combined Greene and Richter "for rapid fluid absorption to expand the implant rapidly to fill the aneurysm." (Office Action, p.3). Rapid fluid absorption is not necessary for expansion of the implant of the present invention. As discussed above, the present invention does not require "rapid fluid absorption to expand the implant" and does not completely fill the aneurysm. Rather, the present invention specifically recites an implant comprising a reticulated elastomeric matrix wherein the implant volume is less than the internal volume of the vascular malformation. The elastomeric matrix of the present invention is capable of being compressed and resiliently recovers without the application of an external force, such as fluid pressure from rapid fluid absorption. The properties of the elastomeric matrix provide a mechanism for the implant to resiliently recover and expand "from a first configuration to a second configuration, the second configuration being larger than the first configuration."

D. Greene Teaches Away from the Present Invention

Moreover, Greene teaches away from the Applicants' claimed invention. Specifically, Greene criticizes implants that fit into a neck of an aneurysm because "they are not easily adapted for precise implantation within a sack-shaped vascular structure, such as an aneurysm, so as to fill substantially the entire volume of the structure." (Greene, col. 3, lines 12-21). In addition, Greene stated in the background section that there had been "a long-felt, but yet unsatisfied need for an aneurysm treatment device and method that can **substantially fill** aneurysms of a large range of sizes, configurations, and neck widths with a thrombogenic medium with a minimal risk of inadvertent aneurysm rupture or blood vessel wall damage." (Greene, col. 3, lines 22-27). In direct contrast to the aneurysm treatment device described by

Greene, Applicants teach that "... in most cases for the healing process to occur, the implant 10 **cannot take up the whole space of the aneurysm**, as this would stop blood flow through the aneurysm which is necessary for the healing processes." (Specification, page 13, lines 6-9). Accordingly, Applicants respectfully submit that Greene teaches away from the present invention and cannot be modified to include an implant defining an implant volume in an expanded configuration, "wherein the implant volume is less than the internal volume of the vascular malformation" as recited by the amended independent claims 63 and 67.

Additionally, Applicants respectfully submit that Greene cannot be modified to include a reticulated elastomeric matrix as recited by Applicants' claims. According to MPEP 2143.01, VI, "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." One of the principles of operation of the hydrogel implant disclosed by Greene is that the implant be compressed and be set "in its compressed configuration by heating and/or drying." (Greene, col. 7, lns. 27-28). As discussed above, an elastomeric matrix cannot be "set" in a compressed configuration by heating and/or drying. To compress the implant of the present invention comprising a reticulated elastomeric matrix, there must be a continuing application of a compressive force. Absent the compressive force, the elastomeric matrix is resiliently compressible and would be capable of resilient recovery. Therefore, to maintain the implant of the present invention in a compressed configuration, there must be a substantial redesign of the implant of Greene, utilizing different principles under which the implant is maintained in a compressed configuration.

II. Response to Obviousness Rejection Under 35 U.S.C. §103(a) over Greene in view of Richter and further in view of Spaans or Slaikeu

Claims 54, 55 and 66 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Greene in view of Richter and further in view of U.S. Patent No. 6,784,273 to Spaans et al. ("Spaans"). Claims 56 and 57 are rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Greene in view Richter and further in view of U.S. Patent No. 6,231,590 to Slaikau et al. ("Slaikeu"). For at least the reasons discussed above, Greene in view of Richter fail to teach or suggest all of the claim elements of Applicants' claims. As demonstrated below, the additional secondary reference cited by the Examiner, Spaans and Slaikeu, do not cure the deficiencies of Greene in view of Richter.

Spaans describes a biomedical polyurethane suitable for implants based on diisocyanate linked polyester(co)polymer and diol components. (*See* Spaans, col. 1, line 65 to col. 2, line 6). In particular Spaans describes polyurethane consisting of repeating units of the following formula:

$$\{C\text{-}(O)\text{-}N\text{-}R_1\text{-}N\text{-}C(O)\text{-}O\text{-}D\text{-}O\text{-}C(O)\text{-}N\text{-}R_1\text{-}N\text{-}C(O)\text{-}O\text{-}E\text{-}O\}_n$$

wherein R_1 is an n-butylene moiety, D is a polyester moiety, E is an n-butylene diol, and n-hexylene diol or a diethyene glycol based moiety and n indicats the number of repeating units. (Spaans, col. 3, lines 15-24). Spaans does not teach or suggest any particular structure for is biomedical polyurethane, much less a reticulated elastomeric matrix as recited by Applicants' claim 1. Moreover, Spaans merely mentions that its material may be suitable for implants, but does not teach or suggest any particular type of medical device. (*See* Spaans, col. 1, line 66). Spaans does not contemplate a device for treating a vascular malformation, much less an implant comprising a reticulated matrix wherein the implant volume is less than the internal volume of the vascular malformation.

Applicants' claim 66 specifies that "said isocyanate component comprises at least one of 4,4'dipheynlmethane diisocyanate and 2,4'-diphenylmethane diisocyanate. Spaans describes polyurethanes containing "aromatic diphenylmethane diisocyanate (MDI)" but does not specifically describe either 4,4'dipheynlmethane diisocyanate or 2,4'-diphenylmethane diisocyanate, as required by Applicants claim 66. In addition, Spaans teaches away from the use of an aromatic diphenylmethane diisocyanate (MDI) in a biomedical device, such as a device for treating a vascular malformation recited by Applicants' claim 63. Spaans considers polyurethanes containing an aromatic diphenylmethane diisocyanate (MDI) as "an important disadvantage." (Spaans, col. 1, line 10-13). Specifically, Spaans states that "MDI based polyurethanes are known to release carcinogenic and mutagenic products on degradation." (Spaans, col. 1, line 13-14).

Applicants' claims 56 and 57 specify a reticulated elastomeric matrix comprising a growth factor (claim 56) or elastin (claim 57). However, the Examiner contends that Slaikeu "teaches an implant may include elastin and/or growth factors (see column 7, lines 15-21) to promote cellular ingrowth between the implant site and the implant itself." (Office Action, p.5). Applicants respectfully disagree.

Slaikeu describes a vaso-occlusion device, such as a coil, at least partially coated with a bioactive agent, a collagenous material, or a collagenous coating optionally containing or coated with other bioactive agents. (*See* Slaikeu, col. 3, lines 7-22). Specifically, Slaikeu describes devices having a vaso-occlusion coil in treatment of an aneurysm, the aneurysm itself may be filled with devices described therein. (*See* Slaikeu, col. 9, lines 12-14). Slaikeu does not contemplate treating a vascular malformation with a device comprising at least one implant comprising a reticulated matrix, as recited by Applicants' claims. There is not teaching or

suggesting in Slaikeu for a reticulated elastomeric matrix, much less a reticulated elastomeric matrix comprising a growth factor or elastin. In addition, Slaikeu provides a complete solution for embolizing an aneurysm using its vaso-occlusion coil and does not teach or suggest any other device for treating a vascular malformation. Slaikeu dos not contemplate a device, as recited by Applicants' claims, comprising at least one implant comprising a reticulated matrix, the implant being expandable from a compressed configuration sized for delivery into the internal volume of the vascular malformation to an expanded configuration that is fitted at least in part to a shape of the internal wall of the vascular malformation.

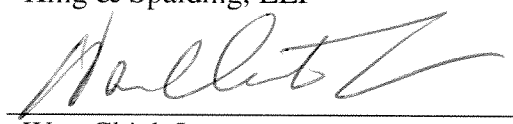
CONCLUSION

Based on the foregoing remarks, Applicants respectfully request withdrawal of the rejections of claims and allowance of this application. In the event that a telephone conference would assist in the examination of this application, Applicants invite the Examiner to contact the undersigned at the number provided.

AUTHORIZATION

The Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to Deposit Account No. **50-3732**, Order No. 14596.105002. In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. **50-3732**, Order No. 14596.105002.

Respectfully submitted,
King & Spalding, LLP



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